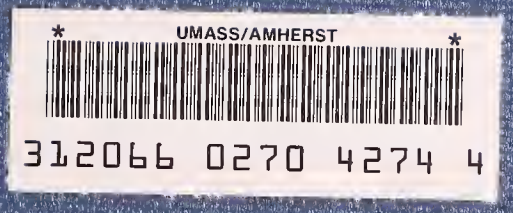

The Commonwealth of Massachusetts
HEALTH FACILITIES APPEALS BOARD
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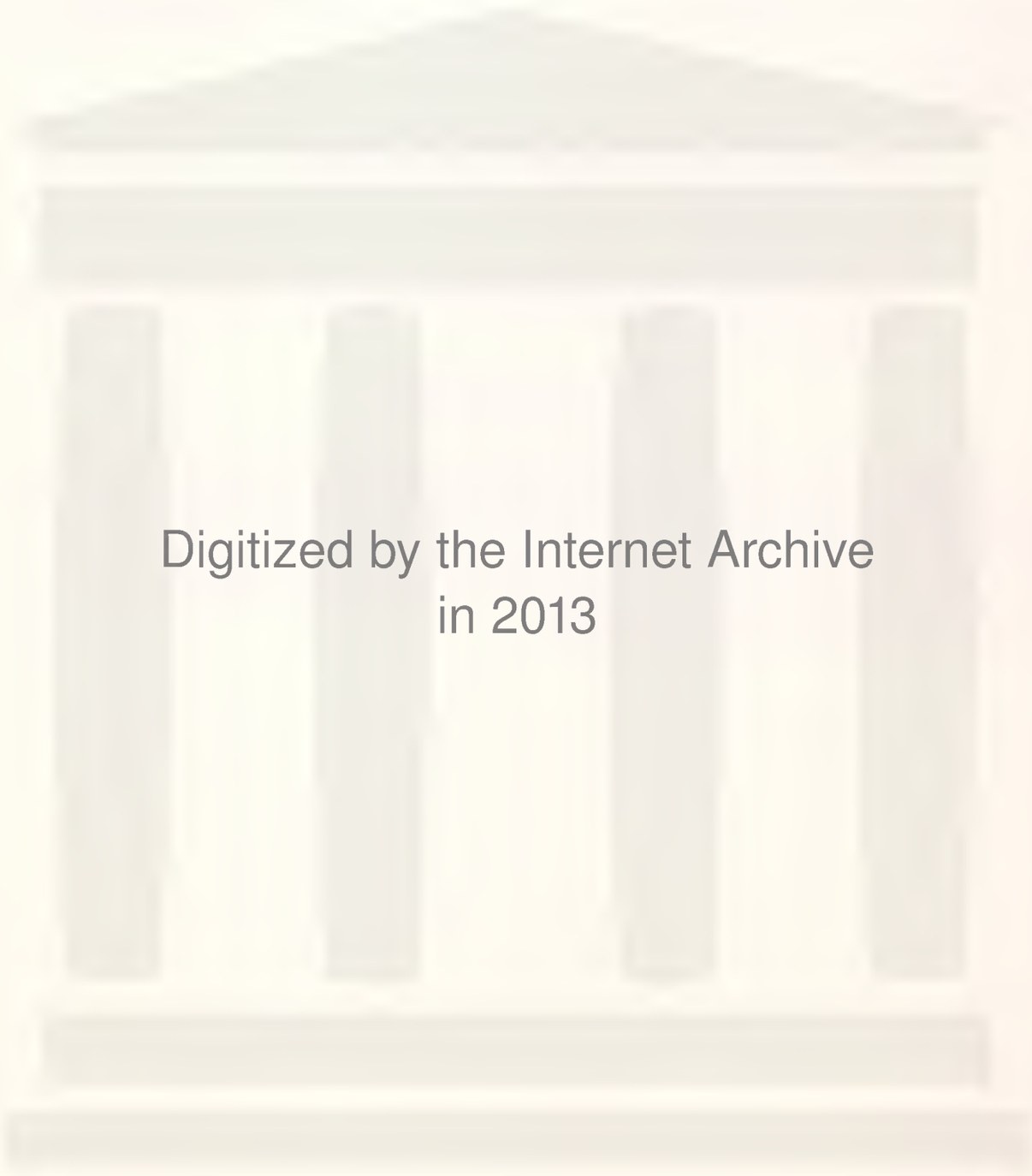
To: **All Parties of Record & HFAB Members**

Date: **June 21, 1989**

Re: **Peter Gordon d/b/a Eastpointe Nursing Center v. DPH, DoN Project No. 4-1129**

Motion to Dismiss

On August 29, 1989, Eastpointe Nursing Center and the Department of Public Health filed a "Stipulation of Dismissal" before this Board. We treat this as a Motion to Dismiss With Prejudice, agreed to by the primary parties to the Appeal filed before this Board on 31 May 1989, and hereby grant the motion subject to agreement by all parties of record. The hearing scheduled for September 6, 1989 is hereby cancelled.



COMMONWEALTH OF MASSACHUSETTS
Health Facilities Appeal Board
Boston University School of Law
765 Commonwealth Avenue
Boston,MA 02215

The Ernest J. Broadbent Ten Taxpayer Group, et al.,
vs.
Department of Public Health
DoN 5-3542

Final Decision

This is an appeal from the Department of Public Health's (the Department) decision approving Charlton Memorial Hospital's (Charlton) DoN applicaton, project number 5-3542, to convert 20 medical/surgical beds to a 20-bed inpatient rehabilitation unit. The appellants consist of the Ernest J. Broadbent Ten Taxpayer Group (Broadbent), whose members have Braintree Hospital affiliations.

Procedural History

On May 1, 1987, Charlton Memorial Hospital of Fall River filed a DoN application with the Department of Public Health to convert 20 medical/surgical beds to a 20-bed inpatient rehabilitation unit. Prior to submitting its proposal, Charlton consulted with Staff from the DoN Program, Southeastern Massachusetts Health Planning and Development, Inc. (HSA V), the Office of Health Policy, St. Anne's Hospital of New Bedford, St. Luke's Hospital of Middleborough and New Bedford, Brockton Hospital and Morton Hospital of Taunton.

In a document dated September 12, 1988, Broadbent submitted a Recommendation of Denial to the Department's DoN Office. Nevertheless, on February 28, 1989, the Department approved Charlton's DoN application by a vote of 4 - 0, with 1 abstention. The Determination was subject to several conditions regarding maximum capital expenditures, equity contribution, the need for Charlton to forward copies of signed referral agreements, accreditation papers, provision of free care and delicensure of the twenty beds currently designated as medical/surgical that are to be designated as acute rehabilitation. Written notice of the decision, dated April 14, 1989, was mailed on April 19, 1989.

On May 3, 1989, the Ernest J. Broadbent Ten Taxpayer Group ("Broadbent") filed this appeal.

Issues on Appeal

Broadbent challenges the Department in seven major areas. It claims:

1. The Department's conclusion that Charlton followed an adequate health planning process was arbitrary, capricious and contrary to 105 CMR 100.533 (B)(1).

2. The Department's conclusion that need existed for Charlton's Project violated the Department's regulations and guidelines and constituted an abuse of discretion.

3. The Department's finding of need for Charlton's Project on the basis of geographic access was arbitrary and capricious.

4. Charlton was already providing rehabilitation services without a DoN, making the Department's approval arbitrary and capricious.

5. Approval would result in waste of public monies and therefore was arbitrary, capricious and contrary to 105 CMR 100.533(B)(5).

6. Charlton failed to demonstrate the relative merit of its proposed project, making the Department's approval arbitrary and capricious.

7. The Department failed to comply with Chapter 23 of the Acts of 1988, making its approval arbitrary and capricious.

To support these claims, Broadbent cites a wide range of evidence, some of which is irrelevant to the scope of the Board's review. We consider only those allegations that might be construed as claims that the Department's decision "was an abuse of the Department's discretion, a failure to observe procedures required by law... or a violation of applicable provisions of law."[1]

Claim 1: Adequacy of the Health Planning Process

Broadbent remonstrates that the hospitals with which Charlton consulted are in Service Area A, as opposed to Service Area B, the area in which Charlton is actually located.[2] Broadbent notes that Charlton "could have and should have" consulted with providers of rehabiliation hospital services in its own service area, and lists Braintree, Lakeville, Barnstable County, and New England Sinai Hospitals as other rehabilitation hospitals in Area B.[3] Broadbent further criticizes the Department's approval of Charlton's contract with a management company as an inadequate proxy for consulting with proximate rehabilitation hospitals. Broadbent submits that the Department's

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[1] 113 CMR 1.01(2)*a); Mass. Gen. Laws, c.111, §25E.

[2] Broadbent Brief at 4.

[3] Broadbent Brief at 4-5.

finding that the applicant engaged in a sound health planning process as required by 105 CMR 100.533 (B)(1), despite this failure to consult with any providers in the appropriate service area and with other rehabilitation service providers, constitutes an abuse of discretion.

The Department disputes the contention that the acute-care hospitals with which Charlton consulted were in Area A; rather, the Department notes that these hospitals are located in Area B.[4] Broadbent did not contest the Department's position that the hospitals with which Charlton consulted were in Area B at the hearing before this Board, so we assume that the Department's statement is correct.

This Board has previously held that when the Department seeks to demonstrate that an applicant's health planning is inadequate, it must have previously established specific criteria by which the planning process can be measured.[5] The Department points out, however, that no such specific standards have been established for planning rehabilitation services. The Department asserts that it would be unreasonable to require Charlton to consult with every acute-care hospital in Area B, or to consult with all of its competitors (Braintree Hospital among them).

We cannot agree with Broadbent that the Department's decision in this matter constituted an abuse of discretion; In South Shore Hospital v. Department of Public Health,[6] the Board faulted the Department specifically for concluding that a DoN applicant failed to "work with other health care providers to consider multi-institutional approaches", when no criteria existed for measuring inter-institutional approaches. Since no specific criteria have been established for developing a multi-institutional approach to the rehabilitative services involved in the current appeal, the Board cannot assume that the efforts which Charlton did make were per se inadequate.

Claims 2 and 3: The Finding of Need

Broadbent takes issue with the Department's finding of need for additional rehabilitation beds. Broadbent's main assertion, emphasized repeatedly in oral argument, was that not only is Broadbent located in an area which the Department itself acknowledges carried a surplus of 127 inpatient rehabilitation beds, but that the figure of 127 surplus beds represents a gross underestimate.[7] To support this conclusion, Broadbent estimates that there are 90 beds at Lakeville Hospital (19 miles from Charlton) and 27 beds at Barnstable County Hospital that meet the Department's own criteria for inpatient rehabilitation beds,[8] but which the Department did not count. Broadbent refers to an Informational Memorandum Regarding Rehabilitation Bed Supply and

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[4]The Department Brief at 2.
[5]South Shore Hospital v. Dept. of Public Health, HFAB Nos. 4-3023 and 4-3025.
[6]DoN Nos: 4-3023 and 4-3025.
[7]Broadbent Brief at 6-7.
[8]Broadbent Brief at 9-10.

Need,[9] in which these criteria are listed. Broadbent then takes note of the Staff's argument that state and county owned hospitals are excluded from the listing of rehabilitation beds "due to their different orientation and their distinct populations", and asserts that there is nothing in "applicable statutes or regulations" that supports this exclusion.[10] Broadbent further cites comments made by the Commissioner of Public Health explaining why the Department considers the Lakeville beds differently.[11] It takes the Commissioner's acknowledgment that "...the Lakeville Hospital's mission has been rehabilitation..." as proof of the Department's arbitrariness in failing to take Lakeville Hospital's 90 rehabilitation beds into account in the bed need formula.

The Department's responds that neither Lakeville nor Barnstable County Hospital has any beds dedicated to the "comprehensive acute inpatient rehabilitation" which Charlton offers; nor are they licensed as rehabilitation beds.[12] Although the Informational Memorandum[13] states that "if any one of these criteria is met, the unit or facility should be included in the listing [of rehabilitation beds]", the Department points out that the memorandum explicitly states that each criterion alone "was not determinative." Moreover, according to the Commissioner,

> "...the mission of our public health hospitals changes over time, and with AIDS and the nursing home bed shortage, the need for metally ill/medically ill patients to be placed in long term care units, the mission may change around our hospitals.... The mission overall of our public health hospitals is evolving as we speak...and the need to have that flexibility is one that deserves attention here."[14]

In oral argument, the Department distinguished chronic rehabilitation services for patients with long-term debilitating disease requiring months or even years of hospitalization, (as are provided by the chronic care hospitals at Lakeville and Barnstable), from acute rehabilitation services, which are specifically targeted to patients who need aggressive therapy and are expected to recover relatively quickly (as are provided by Charlton).

The Board notes that the Department's decision to grant Charlton's DoN does not hinge solely on whether these chronic beds are required to be counted as part of the available rehabilitation bed supply. Even without inclusion of the chronic care beds, the staff analysis shows a surplus of 127 inpatient rehabilitation beds in Service Area B. It is not clear that the failure, even if error, to include chronic care beds in the public hospitals would have materially affected the staff recommendation. Charlton's approval was not driven by a particular bed count, but by the staff recommendation that there

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[9]Dated January 24, 1989 from Janet M. Kelly, Senior Program Analyst to Commissioner Prothrow-Stith through Susan K. Glazer, Program Director, Determination of Need Program.

[10]Broadbent Brief at 8.

[11]Broadbent Brief at 8.

[12]The Department Brief at 5.

[13]The Department Brief at 6.

[14]Public Health Council Meeting Minutes at 11-12.

were problems with access to currently available beds, creating a specific need for beds in the Fall River/New Bedford geographic area.

The Department's January 24, 1989 Informational Memorandum contemplates approval of some applications despite an existing surplus of rehabilitation beds, given "compelling arguments regarding specific conditions, such as problems with geographic access to an existing rehabilitation program..." The staff recommendation states that access problems exist in the Fall River/New Bedford area, where 24% of the total population is projected to be elderly by 1995 and where there are no approved rehabilitation beds.

The Department argues that in considering whether access problems exist, one must consider (in addition to raw distance) such factors as travel times and public transportation availability. The record is extremely sparse with regard to these issues, and one might question whether this data alone is sufficient to establish that an access problem exists. However, the Department sets forth an additional reason for finding need, in that approval of Charlton's DoN request reduces excess Medical/Surgical capacity in the area by 20 beds. The Department is required by the DoN regulations[15] to consider such factors as geographic barriers and the capability of projects to "promote and further consolidation of facilities and services within the applicable service area consistent with the objectives of the determination of need process."

The Board finds the Department's finding of need to be within the scope of the Department's authority, given the approval's specific citations of access problems and the potential for reducing excess medical/surgical bed capacity, and the charge in the regulations to consider such issues in determining compliance with Factors 2 and 3. However, the Board cautions the Department on the need to document the existence of conditions cited in its analyses fully. The Board also recognizes that the Department's criteria used to define rehabilitation beds will demand greater clarity as experience is gained with varying intensities of rehabilitation services.

The full text of the Department's Informational Memorandum states:

> "...as stated previously, the Questionnaire included questions regarding CARF accreditation, exemptions from the Prospective Payment System, and licensure by the Department. These three criteria were used together, and individually, in order to determine whether a unit or facility should be included in the rehabilitation bed supply. The reasons that each criteria [sic] was not determinative are as follows..."[16]

In subsequent paragraphs, the memorandum discusses each of the three criteria at greater length along with examples; however, each example involved beds counted as rehabilitative even though they did not fit all three criteria. No example is given of beds fitting all three criteria but not counted as rehabilitative. One can argue that the Department intended to provide the most desirable criteria for defining rehabilitation beds, which could be relaxed in some cases, rather than to set forth criteria that would

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[15] 100.533(B).

[16] Informational Memorandum at 5.

be insufficient in some cases. Nevertheless, the Department made no definitive rules governing application of these criteria to define rehabilitation beds.

The Board agrees with the Department that the Commissioner has authority to define the types of admissions to Lakeville Hospital, a state hospital, and finds no abuse of discretion in the Department's distinction between beds devoted to rehabilitative care of a chronic versus an acute nature. The Board finds the Department's desire to define sub-categories of rehabilitation beds reasonable, but urges the Department to articulate the implications of this policy on the calculation of need for the guidance of future applicants.

Claims 4 and 7: Failure to Comply with Licensure by Service Regulations and Chapter 23.

Broadbent challenges approval of Charlton's DoN application on the ground that Charlton admitted that it was already providing rehabilitation services, although not licensed to do so.[17] Broadbent contends that neither Charlton nor the Department "should be permitted to utilize that illegality to justify a DoN project approval."

The Department counters by outlining the history of passage of Chapter 23 and the intent of the drafters regarding conversions. One of the purposes of the DoN law was to reduce costs in the health care system, and by converting costly excess acute-care capacity to less costly rehabilitation services, expenditures can be saved in accordance with the intent of Chapter 23.[18] No rules explicitly forbid DoN approval of conversions which have already taken place historically, but informally. Department's approval of a *fait accompli*, under the specific circumstances of this case, is not arbitrary, capricious or a violation of applicable statutes or procedures.

Claim 5: Waste of Public Monies and Understated Real Costs Associated with the Project

Broadbent accuses Charlton of applying for the conversion in order to escape DRG reimbursement constraints, and thus receive cost-based reimbursement for its rehabilitation patients. Broadbent asserts that higher reimbursement would be at the public expense, contrary to the cost savings objectives of the DoN Program. Broadbent then predicts that approval of the proposed rehabilitation beds will jeopardize the ability of Lakeville Hospital to attract similar rehabilitation patients, which Broadbent states "should be" the mission of Lakeville.

Broadbent also criticizes the management contract that Charlton had arranged, noting primarily that the per diem rate of $70 is "high", and higher than the highest per diem fee that Braintree Hospital has ever charged ($60). Broadbent goes through several additional calculations, arriving at figures that imply high management profits and other operating costs that would be passed on to the public. [19]

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[17] Broadbent Brief at 14-16.

[18] The Department Brief at 4-5.

[19] Broadbent Brief at 21-25.

Finally with regard to costs, Broadbent notes that the Department's approval letter stated that "all operating costs are subject to further review by the Rate Setting Commission according to their [sic] policies and procedures." Broadbent then points to a communication from the Department DoN Program Specialist regarding contact with the Rate Setting Commission (RSC), in which the Specialist noted that it was "not settled how RSC looks at these [operating costs for rehabilitation units] . . . ." Broadbent reasons that if the Department cannot rely on the RSC to correct costs accurately, the Department is not fulfilling its responsiblity under 105 CMR 100.533 (B)(5) to assess the reasonableness of operating costs associated with a DoN project.

The Department rebuts these arguments in various ways. First it discusses the Department's authority and dismisses Broadbent's assertions about what the mission of Lakeville Hospital should be as irrelevant.[20] Second, it contends that Broadbent provided no evidence to suport its assertion that the $70 per diem fee was high. The Department responded to each of the financial projections supplied by Broadbent, contending they are based on inappropriate assumptions regarding cost-shifting and ignoring the ability of the Public Health Council to control certain costs.[21]

The Board agrees with the Department regarding its authority to determine the mission of Lakeville Hospital, and, specifically, the utilization and target population of its rehabilitation beds. As stated previously, the Board also accepts the reasonableness of the Department's need to distinguish "chronic" from "acute" rehabilitation beds. The Board also agrees, in general, with the Department's position that Broadbent failed to demonstrate that Charlton's management contract with New England Rehabilitation Management would pass excess costs on to the public. Broadbent's bald assertion that the $70 per diem fee was "high" was unsupported by substantial evidence.

Claim 6: Charlton Failed to Demonstrate Relative Merit

Broadbent asserts that Charlton failed to provide evidence in support of the relative merit of its proposed project. Indeed, there was little discussion in the DoN application of the inpatient or outpatient services supplied by other providers.[22] 105 CMR 100.533 (B)(7), which outlines conditions regarding relative merit, requires the Department (not the applicant) to consider proposals with respect to the needs of the entire system.[23] Broadbent's argument must therefore fail.

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[20]The Department Brief at 7-8.
[21]The Department Brief at 10-12.
[22]Broadbent Brief at 26.
[23]The Department Brief at 12-13.

Conclusion

In summary, we find no merit to Broadbent's claims that the Department's approval of Charlton's DoN application was arbitrary, capricious, an abuse of discretion or in violation of applicable law or procedure. We note, for the record, that the criteria the Department uses to define rehabilitation beds need greater clarity. This will no doubt serve as a focus for further contention unless clearer guidelines are drafted.

The appeal is denied.

Health Facilities Appeals Board
August 29, 1989

[Wendy Mariner did not participate in decision of this appeal.]

COMMONWEALTH OF MASSACHUSETTS
HEALTH FACILITIES APPEALS BOARD
Boston University School of Law
765 Commonwealth Avenue
Boston, Massachusetts 02215

NATIONAL MEDICAL CARE, INC., d/b/a BMA OF WESTWOOD

v.

DEPARTMENT OF PUBLIC HEALTH

DoN Project No. 4-4730

This is a second appeal by National Medical Care, Inc., d/b/a BMA of Westwood (NMC), of a Public Health Council (the Department) decision to condition approval of NMC's application for a Determination of Need (DoN) for construction of a new dialysis facility in Westwood, Massachusetts, upon NMC's providing patients with access to "single use dialysis" in the new facility.[1] In our decision dated January 19,

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[1]Hemodialysis (dialysis) is a process employing a dialyzer or artificial kidney, consisting of a plastic filter, membrane and tubing, to purify the blood of persons with renal disease whose kidneys are unable to perform this essential function. Patients with end stage renal disease require dialysis lasting several hours three times a week. Single use dialysis refers to using a dialyzer once, then discarding it. Reuse refers to using the same dialyzer several times for the same patient; the dialyzer is disinfected between uses.

The "single use" condition reads as follows:

> 5. BMA of Westwood shall provide access to single use dialysis, including patients already dialyzing at the facility.
>
> a) All patients entering the facility or already at the facility shall be informed of this choice in writing.
>
> b) Patients desiring single-use dialysis shall not be discriminated against either in access to the facility or in access to convenient dialysis times.
>
> c) In conformance with 105 CMR 100.522(B), the facility shall file the required reports concerning this condition with the DoN Program Director as well as with the Michael E. Lisieski Ten Taxpayer Group.

1988,[2] on NMC's first appeal, this Board found that the Department abused its discretion in requiring NMC to offer single use dialysis as a condition of approving its DoN application. We reversed the Department's decision and remanded the case to the Department for reconsideration or removal of the condition. On September 20, 1988, the Department reaffirmed its original decision to require that single use dialysis be offered to patients of NMC. In addition, it stated that this condition is to be imposed on all future dialysis applications. NMC now appeals from this decision on reconsideration by the Department.

NMC argues that the Department acted beyond the scope of its authority in imposing the condition, and that the imposition of the condition violated the Administrative Procedures Act and M.G.L. c. 111, section 25F. NMC also contends that the requirement creates an inequitable system in the Commonwealth whereby some but not all dialysis facilities are required to offer single use, and that the condition is impliedly preempted by the legislative and regulatory scheme established under the Medicare Act. We agree that the Department acted beyond the scope of its authority in applying a regulation of general and future effect, not adopted in compliance with requirements of law, in the guise of a condition on NMC. We find further that the Department abused its discretion in imposing the condition on NMC.[3]

In this appeal, the Department makes explicit its rationale for imposing the single use condition. The condition was imposed for the sole purpose of enabling patients to choose whether their dialysis regimen would employ single use dialyzers (i.e. artificial kidneys) or dialyzers that are used more than once for the same patient. The Department concluded that patient choice in this matter is desirable because "patient participation facilitates more successful overall plans of care for dialysis patients that may result in more successful outcomes," and that dialysis patients should be

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[2] *National Medical Care, Inc. d/b/a BMA of Westwood v. Department of Public Health*, DoN Project No. 4-4730, Final Decision, January 19, 1988 (*National Medical Care I*).

[3] We do not agree that the condition is preempted by the federal End Stage Renal Disease program enacted as part of the Medicare Act. Federal law may preempt state law (1) by an explicit statutory statement of the scope of preemption; (2) by occupying an entire field of regulation with no residual power left to the states; or (3) by creating a conflict in which compliance with state law creates an obstacle to Congressional goals. *Michigan Canners and Freezers Assoc. v. Agricultural Marketing and Bargaining Board*, 476 U.S. 461, 469 (1984). NMC concedes that "Congress has not expressly forbidden nor completely displaced regulation in this specific area." NMC Brief at 11. The first two bases for finding preemption are therefore inapplicable. NMC's argument rests on the third criterion, that the Department's action "stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress." *Id.*, citing *Fidelity Fed. Savings and Loan Ass'n v. De la Cuesta*, 458 U.S. 141 (1982). There is nothing in the federal legislation or regulations indicating that the objectives of the federal ESRD program require dialysis facilities to determine for themselves whether they will provide single use dialysis in addition to or instead of reuse dialysis. While the federal program regulates the use of reused dialyzers, it does not preclude single use. Neither would proper state legislation that required single use dialysis create any obstacle to the objectives of the federal ESRD program. NMC's contentions on this point are without merit.

considered vulnerable patients for whom providers may be required to make extra efforts to preserve autonomy and dignity.[4] We do not mean by this decision to cast any aspersion on respect for patient autonomy. However, mere respect for patient autonomy is insufficient to justify the Department's action in this case.

First, the record does not support the Department's conclusions concerning the effect of patient choice about reuse or single use dialysis. Second, the condition was not imposed to correct any deficiency in NMC's application, or to ensure that the health services offered by NMC would meet the requirements of the DoN program. Rather, it was a new policy initiative to incorporate patient choice as a desirable element in all dialysis services for all patients in the Commonwealth. The ideal of patient choice, by itself, is not a sufficient basis for conditioning an individual applicant's DoN on provision of a particular form of medical care.

The Department does not argue that patient choice of single use dialyzers is necessary to satisfy the DoN requirements for a dialysis facility. Rather, it argues that it has discretion to impose the condition because the requirement is consistent with Departmental regulations and guidelines governing the determination of need for dialysis facilities. Specifically, the Department relies on a sentence in its DoN Guidelines for End Stage Renal Disease (ESRD Guidelines), which provide additional information for prospective dialysis facilities to comply with Factor 3 (Operational Objectives of the DoN regulations).[5]

The ESRD Guidelines' discussion of Factor 3 focuses on efficient and effective operation to assure dialysis patients "effective and relatively convenient" services. It refers specifically to four measures of compliance with the operational objectives: home dialysis training programs; written affiliation agreements for inpatient emergency care; laundry, social and dietetic services; and procedures for dialysis of patients with hepatitis.

The four-sentence discussion of these operational objectives includes the statement on which the Department bases its decision: "The treatment environment should be flexible in order to meet the medical, social and psychological needs of patients." The Department contends that "psychological needs" includes patient choice of single use dialyzers. The term "psychological needs" is not defined, and we have not been referred to any history or interpretation of the term or to any indication that the Department ever considered patient choice of single use dialyzers when the

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[4]Department of Public Health, Notice of Remand Decision, May 5, 1989.

[5]Department of Public Health, Determination of Need Guidelines for End Stage Renal Disease (ESRD), adopted June 1985. Applicants for a DoN must demonstrate compliance with eight factors. 105 CMR 100.533. Factor 3 provides: "The project will produce a facility or service which is capable of operating efficiently and effectively and which relates to other facilities and services so as to promote and further coordination and consolidation of facilities and services within the applicable service area consistent with the objective of the determination of need process."

Guidelines were adopted.[6] The brief discussion in the ESRD Guidelines on Factor 3 suggests that the term most likely refers to scheduling times for dialysis that are convenient for patients and, perhaps, reasonable privacy during dialysis. There is no indication that the term refers to the specific provision of dialysis with dialyzers that are used only once. The ESRD Guidelines cannot be interpreted to give reasonable notice to DoN applicants that compliance with program requirements, and Factor 3 in particular, requires providing patients with the option of single use dialysis. Thus, the condition was not and could not have been imposed to cure a defective application.[7]

Thus, the issue is whether the condition is a justifiable exercise of the Department's authority under the general DoN regulations. These regulations permit the Department to "reasonably prescribe" conditions that are consistent with the objective of the determination of need program[8] to allocate health care resources and improve health care delivery systems "such that adequate health care services are made reasonably available to every person within the Commonwealth at the lowest possible cost."[9]

There is no dispute that reuse dialysis is an accepted and effective method of dialysis.[10] Therefore, the single use condition was not necessary to ensure the provision of "adequate health care services." Neither was it necessary to achieve "the lowest possible cost." There is some indication in the record that requiring facilities to offer single use dialysis will generate costs that may not be fully reimbursed by Medicare under the federal End Stage Renal Disease program.[11] Moreover, the

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[6]Federal regulations governing ESRD facilities refer generally to personalizing a patient care plan for each patient to reflect the patient's psychological, social and functional needs, 42 CFR 405.2137(b)(1), and giving "due consideration . . . to his preferences." 42 CFR 405.2137(b)(3). The terms are undefined here as well, but there is no suggestion that they require facilities to offer single use dialysis. The regulations contemplate that facilities will offer reuse. Section 405.2138(a)(4) requires that patients be "fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers." Subsection (b)(1) of that section requires that patients be afforded the opportunity to participate in the planning of their medical treatment, indicating that participation in planning does not preclude employing reuse. Medical record provisions require that the medical record state whether the patient is treated with a reprocessed hemodialyzer. 42 CFR 405.2139(a). Section 405.2140(b)(1) requires written policies for the sterilization of reused supplies and section 405.2140(c) provides for records of their cleaning and storage. Finally, all facilities that reuse dialyzers must comply with the July 1986 practice guidelines of the Association for the Advancement of Medical Instrumentation and additional procedures. 42 CFR 405.2150.

[7]The Department does not suggest that NMC did not comply fully with Factor 3.

[8]105 CMR 100.550.

[9]105 CMR 100.532.

[10]As was the case in *National Medical Care I*, the safety or effectiveness of reuse was not at issue before the Department and is not challenged in this appeal.

[11]End Stage Renal Disease Program, Pub. L. 95-292.

Department accepted as true the proposition that imposing the single use requirement would not produce dialysis services "at the lowest possible cost" as that term is used in the statement of DoN objectives. Rather, the Department argues that the single use condition is valid even if it increases health care systems costs because financial costs are not the sole determinant of a DoN decision. The Department is correct in stating that costs are not the only factor to be considered in making determinations of need. The issue presented in this appeal, however, is whether the condition imposed on an otherwise satisfactory application was "reasonably prescribed" and consistent with the dual objectives of reasonable availability of adequate health care and lowest cost. Thus, the Department cannot simply posit patient choice as a new factor to be considered in making determinations of need. It has the burden of establishing that requiring single use is a reasonable condition that will further the dual objectives of the DoN program. Moreover, it must establish that the condition is appropriate to impose on a particular applicant, NMC in this case.

The Department's September 20, 1988, reconsideration of the question of imposing the condition on NMC consisted largely of deciding that the matter had been discussed adequately at its original meeting on July 21, 1987. But this Board had already determined that the record contained "no reasonable basis" for imposing the condition in the first place.[12] If the Department's decision of September 20, 1988, simply expresses disagreement with the Board's decision on appeal, it cannot stand.

However, the Department appeared to consider specific evidence with respect to the desirability of imposing the condition. A new Staff Summary was prepared and presented at the September 20, 1988, meeting "to present additional information to substantiate Staff's finding that patient choice is a valid reason for imposing a single use condition."[13] Staff concluded that "the literature supports the *theory* that patient participation in treatment choices facilitates more successful overall plans of care for dialysis patients that *may* result in more successful outcomes."[14] Yet the literature reviewed does *not* support any inference that dialyzer reuse is harmful or even less safe or effective than single use. At most it confirms the ethical principle that patients should be free to choose what medical treatment they will undergo, but that when the choice is between equally effective medical procedures, the choice has no demonstrable effect on treatment outcomes.[15]

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[12]*National Medical Care I* at 2.

[13]Staff Summary dated Sept. 20, 1988, at 3. Significantly, the Staff Summary prepared for the original Department meeting of July 21, 1987, recommended against imposing the single use condition on NMC on the grounds that enough other dialysis facilities would offer single use to afford patients with "freedom of choice." *National Medical Care I* at 4, n. 8.

[14]Staff Summary dated Sept. 20, 1989 at 6. (emphasis added).

[15]Indeed, the literature reviewed indicates that outcomes are often better with reuse than with single use dialysis. *Id.*

The Department expressly relied on its perception of the expected psychological value to all patients of having the right to determine whether to dialyze with single use or used dialyzers. The literature speculates that choices concerning other types of treatment may enhance patient satisfaction because patient participation in their care may improve their sense of well being by giving them some control over their care. By and large the literature is directed at the professional practice of physicians and other health care professionals who care for dialysis patients, and properly admonishes them to treat patients with respect and to encourage participation in their treatment program. This is or should be true of all health care professionals. However, it does not establish that the psychological needs of ESRD patients require that *patients* decide that the facility must use dialyzers only once.[16]

The reasons considered by the Department for imposing the single use condition on NMC are applicable to all dialysis patients. There was no discussion of the patient population likely to be served by the NMC Westwood facility, or of whether patient choice with respect to single use or reuse dialysis was of special concern to this population. Rather, the condition was imposed because of the Department's view that most patients in the Commonwealth would prefer to choose whether or not their dialyzer would be reused in any facility, and that the ability to choose would be likely to enhance patient satisfaction. Thus, the condition imposed on NMC was not crafted specifically for NMC, but was applied to NMC as a matter of general policy.

The Department expressly decided and stated in its Notice of DoN that the single use condition would be imposed "on all future dialysis applications."[17] There can be no doubt that the Department's statement is a "regulation" subject to the requirements of the Administrative Procedure Act (APA).[18] As defined in the APA, a regulation includes "[any] other requirement of general application and future effect,...adopted by an agency to implement or interpret the law enforced or administered by it."[19] Both the APA and the DoN regulations prescribe specific procedures for the promulgation of such regulations. None of these procedures was followed by the Department. Therefore, the Department's statement can have no force or effect as a regulation for general application for future effect.[20] Specifically, it cannot apply as such to NMC.

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[16]Our conclusion in no way denigrates the rights of patients to choose which, if any, treatment methods they will undergo. This includes the right to refuse dialysis with reused dialyzers. It should be clear, however, that a patient's right to choose among or refuse available alternatives does not by itself generate a legally enforceable duty on the part of any provider to offer or make available any particular treatment or service.

[17]Dept. of Public Health, Notice of Remand Decision, May 5, 1989.

[18]Mass. Gen. Laws Ann. c 30A.

[19]*Id.* at section 1(5).

[20]This does not preclude the Department from promulgating a DoN regulation in compliance with the requirements of the APA in the future, provided that it is able to demonstrate that the regulation will further the objectives of the DoN program.

The Department attempted to accomplish by means of a condition on a particular applicant what it had failed to do by regulation.[21] In so doing, it acted beyond the scope of its authority.

The Department's authority to prescribe conditions to determinations of need does not give it *carte blanche* to require applicants to provide any and all forms of equipment or services that might be desirable. Under section 100.550 of the regulations, the conditions must be prescribed "reasonably," consistent with the objectives of the DoN program.[22] Under section 100.552(A), the conditions must be "reasonably related to the scope of the project and within the control of the applicant" as well as consistent with the objectives of the DoN program.[23] The Department's interpretation of this authority would grant it virtually unbridled discretion to impose conditions on determinations of need.[24] This is inconsistent with the overall purpose of the determination of need program. Moreover, it would grant to the Department almost arbitrary power that is the essence of regulatory abuse.

The decision of the Department is reversed and the matter is remanded to the Department for issuance of a determination of need to NMC without the single use condition.

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[James Hall did not participate in this decision.]

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[21]The Department states that it has imposed the same single use condition on other applicants since issuing the NMC DoN. Far from justifying the condition, this action confirms that the Department was creating general policy without compliance with the requirements for promulgating general regulations.

[22]105 CMR 100.550.

[23]105 CMR 100.552(A).

[24]Patient choice may be as important to patients with other conditions as it is to dialysis patients, even if the treatment available is not life-sustaining. This does not mean that the Department may require new health care facilities to provide whatever equipment patients may prefer if existing alternatives are adequate. This would turn the DoN program on its head, converting it into a guarantor of services regardless of need.